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In re Application of Dane K. Fisher et al.   :
Serial No.: 09/394,745   :
Filed: September 15, 1999   : PETITION DECISION
Attorney Docket No.: 16517.001/38-   :
21(15454)B   :

This is in response to applicants' renewed petition, filed April 14, 2003 under 37 CFR 1.144, requesting withdrawal of the restriction requirement set forth by the examiner.

BACKGROUND

A review of the file history shows that this application was filed under 35 U.S.C. 111 on September 15, 1999. The application, as filed, contained claims 1-7. A preliminary amendment canceled claims 1-7 in favor of new claims 8-11. On December 19, 2000, the examiner mailed a restriction requirement dividing the claims into 2 groups, and requiring a further election of a single combination of nucleotide sequences for examination should Group I be elected. In the response filed April 17, 2001 and the supplemental response filed November 30, 2001, applicants elected Group I, claims 8-10, and a combination of 100 nucleotide sequences. Applicants traversed the restriction on the grounds that it would not be a burden to also examine claim 11, nor would it be a burden to search 498 sequences. Applicants argued that they had searched all of the sequences in a short amount of time and had submitted the results of the search on CD-ROM with the preliminary amendment. On March 18, 2002 the examiner mailed a first action on the merits. The examiner agreed to examine all the pending claims but, with regard to the election of a single combination of sequences, made the restriction final, stating that the USPTO conducts its own search using a different methodology. The Office action indicated that SEQ ID NO: 5893 is free of the prior art. Applicants responded on June 18, further arguing that requiring applicants to file multiple applications would pose an undue hardship. In the Office action mailed September 11, 2002, the examiner maintained that the restriction requirement was in accordance with MPEP 803.04. Applicants filed a petition January 10, 2003 under 37 CFR 1.144, requesting withdrawal of the restriction requirement. This petition was denied in a decision mailed February 14, 2003.

DISCUSSION

Claims 8-10 are drawn to a microarray having fixed thereto a collection of nucleic acid molecules comprising one or more sequences from a list of 497, or portions thereof. Claim 11 is drawn to a microarray having fixed thereto a collection of nucleic acids comprising each of a list of sequences, or portions thereof. The essence of applicants' arguments appears to be that the Office is required to conduct a prior art search of all 497 sequences.

First, applicants argue that the examiner, by forcing applicants to elect a single combination of sequences for examination, has narrowed the scope of the claims. This is correct, and that was the purpose of the restriction requirement. MPEP 803.04 states, in part:

> Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C.121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Complete examination of claims 8-10 as written would require examination of 497 unrelated, independent and distinct inventions in a single application. Because the Office does not have the resources for such an undertaking, USPTO policy is to require applicants to elect a single combination for examination, as set forth in MPEP 803.04. The examiner has correctly applied the prescribed procedure for making a restriction requirement. The examiner determined that one of the sequences in the elected combination, SEQ ID NO: 5893, is free of the prior art. Therefore the elected combination is free of the prior art. The previous petition decision pointed out that any combination comprising SEQ ID NO: 5893 would also be free of the prior art and, therefore, additional combinations besides the one initially elected would be examined so long as they included this sequence.

Applicants argue that claim 8 includes a Markush group and therefore MPEP 803.04 does not apply. Applicants reason that claim 8 does not recite a combination of sequences, but a group of many possible combinations. This argument is not persuasive because example C is also a Markush group containing many possible combinations of sequences:

> (C)   a combination of DNA fragments, said combination containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

Applicants selectively quote MPEP 803.02 to support their position. A more complete selection from this section reads as follows:

> If the members of the Markush group are **sufficiently few in number** or **so closely related** that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206

USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). **Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.** (Emphasis added.)

The 497 sequences recited in the claims are neither few in number nor closely related. Whether the sequences have any patentable utility at all is a question for the Board of Patent Appeals and Interferences but, in any event, applicants have not disclosed any shared substantial structural feature essential to the utility they have asserted for the sequences. Therefore the claims do not meet the necessary criteria to have all members of the Markush group examined together.

Finally, applicants argue that the restriction requirement is unfair. Applicants' arguments are essentially that the restriction practice set forth in the MPEP is bad public policy and abridges their constitutional rights. This line of argument is not persuasive. Whether the restriction practice mandated by the MPEP is "good" or "bad" public policy will not be debated in this decision. This is the procedure that the examiner is directed to follow, and the examiner has correctly followed the procedures set forth in the MPEP. It is possible that the proposed changes in examination practice discussed in the petition will be implemented at some point in the future. If so, these changes will apply equally to all applicants. Until that time, it would not be fair to deviate from prescribed examination procedure on a case-by-case basis.

DECISION

Applicants's petition is **DENIED** for the reasons set forth above.

The application will be forwarded to the examiner for consideration of the Appeal Brief.

Any request for reconsideration or review of this decision must be made by a renewed petition and must be filed within TWO MONTHS of the mailing date of this decision in order to be considered timely.

Should there be any questions with regard to this letter please contact Bruce Campell by letter addressed to the Director, Technology Center 1600, Washington, DC 20231, or by telephone at (703) 308-4205 or by facsimile transmission at (703) 746-5006.

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